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14 **UNITED STATES DISTRICT COURT**
15 **NORTHERN DISTRICT OF CALIFORNIA**
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17 MOLLY BROWN, PARSA MILLER, and
18 LAUREN MORGAN as individuals, on behalf
of themselves, the general public and others
19 similarly situated,

20 Plaintiff,

21 v.

22 NATURE'S PATH FOODS, INC.,

23 Defendant.
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Case No. 4:21-cv-05132-HSG

CLASS ACTION

**DEFENDANT NATURE'S PATH
FOODS, INC.'S NOTICE OF
SUPPLEMENTAL AUTHORITY**

Defendant Nature's Path Foods, Inc. ("Nature's Path") submits this Notice of Supplemental Authority in support of its Motion to Dismiss, filed on August 27, 2021 (ECF No. 18.). Plaintiffs filed their Opposition on September 17, 2021 (ECF No. 23), and Nature's Path filed its Reply on October 7, 2021. (ECF No. 26.)

Plaintiffs Complaint alleges that the labels of more than 50 Nature's Path products are false and misleading to the extent that they overstate the amount of protein in the products. (ECF No. 1, ¶ 48.) Plaintiffs allege that Nature's Path should have calculated protein content on the front labels of its products using the "amino acid" method or adjusting for protein quality using the Protein Digestibility Corrected Amino Acid Score ("PDCAAS"). (ECF No. 1, ¶ 3; 35; 42.) In its Motion to Dismiss, Nature's Path argued that FDA regulations permit Nature's Path to calculate front label protein claims using the Plaintiffs' preferred amino acid method *or* the nitrogen method. (ECF 18 at 7.) Nature's Path explained that Plaintiffs' attempt to require Nature's Path to use the amino acid method was therefore contrary to FDA regulations and preempted.

Nature's Path respectfully notifies the Court of recently-posted guidance from the Food & Drug Administration confirming Nature's Path's understanding of the FDA regulations as permitting either the nitrogen method or the amino acid method for calculating protein content for front label claims. As such, Plaintiffs' claims are preempted. On January 11, 2022, the FDA posted a web page titled "Industry Resources on the Changes to the Nutrition Facts Label." A true and correct copy of the FDA's guidance is attached as **Exhibit A**¹. The web page states:

The web page states:

Label Claims

There are separate methods for determining the number of grams of protein in a serving for declaration on the Nutrition Facts label and for determining the percent Daily Value of protein for the Nutrition Facts label (21 CFR 101.9(c)(7)).

¹ <https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label#LabelClaims> (noting that the content is current as of 01/11/22 and the "following are resources and the most frequently asked questions we have received via our inquiry form, and during presentations made to various stakeholder groups.").

Which method should be used when calculating protein values for use in protein nutrient content claims?

The regulation for nutrient content claims in 21 CFR 101.13(o) states that, except as provided in 21 CFR 101.10, compliance with requirements for nutrient content claims in this section and in the regulation in subpart D of this part, will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in 21 CFR 101.9.

By design, 21 CFR 101.9(c)(7) specifically provides for two different methods for determining protein values. The regulation states, in 21 CFR 101.9(c)(7), that protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International," except that when official AOAC procedures described in 21 CFR 101.9(c)(7) require a specific factor other than 6.25, that specific factor shall be used. Additionally, 21 CFR 101.9(c)(7)(ii) provides the method for determining protein content using the protein digestibility-corrected amino acid score for use in calculating the percent Daily Value.

Determination of compliance for protein nutrient content claims will be based on the use of the methods provided in 21 CFR 101.9(c)(7), including either of the methods mentioned above.

Dated: January 21, 2022

MORRISON & FOERSTER

By:



CLAUDIA VETESI

Attorneys for Defendant
NATURE'S PATH FOODS, INC.